REMARKS

FORMAL MATTERS:

With entry of this paper, claims 1, 3-13, 15-19 and 43-47 are pending in the instant application. Claim 2 is canceled without prejudice.

Claims 1 and 18 are amended to better articulate Applicants' invention. The claim amendments presented do not add new matter. Support for these amendments may be found throughout Applicants' specification, particularly in paragraphs 23, 39 and 45, and claim 2 of Applicants' originally filed application.

Applicants respectfully request reconsideration of the pending claims in view of the amendments and remarks presented herein.

REJECTIONS UNDER §102 – DARDICK ET AL.

Claims 1, 2, 5, 7-9, 12, 16-19 and 43-47 are rejected under 35 U.S.C. §102(b) as being anticipated by Dardik et al. (U.S. Patent No. 3,988,782).

Dardik is interpreted by the Office as anticipating the claim language where the graft of Dardik is semirigid and capable of being attached to a leaflet to the extent that the functional language implies, citing to Figures 5 and 6 and column 5, line 15 to column 6, line 61. The Office rationalizes that as "the graft would be attached to one leaflet and unattached to another or opposing leaflet, it would inherently not affect the mobility of the opposing leaflet because it would not be attached thereto." Applicants do not acquiesce to the rejection, but in a spirit of cooperation with the Examiner, and a mutual interest in expeditious prosecution, Applicants have amended independent claims 1 and 18 to more clearly articulate the meaning of the original claim language. In view of these amendments, Applicants respectfully traverse the rejection.

Applicants respectfully submit that Dardik can not anticipate Applicants amended claims because the grafts discussed in Dardik lack the physical characteristics necessary to provide the

structural elements required to perform as a prosthetic for valve repair as claimed by Applicants. In support, Applicants respectfully direct the Office to the Dardik specification itself:

> "In our copending Application Ser. No. 543,462 filed Jan. 23, 1975, methods of treating the umbilical cord chemically have been disclosed. However, the previous application was directed primarily toward the use of umbilical cord vessels in vascular surgery, such use requiring that the umbilical cord vessels withstand pulsatile pressures. Synthetic mesh reinforcement of the cord vessels was disclosed. However, the previous application was directed primarily toward the use of umbilical cord vessels in vascular surgery, such use requiring that the umbilical cord vessels withstand pulsatile pressures. Synthetic mesh reinforcement of the cord vessels was disclosed. The present invention is directed toward a wider spectrum of uses in which the strength requirements are less severe."
>
> Col. 5, lines 44-51.

Applicants submit that if Dardik's treated umbilical chord is admittedly incapable of serving directly as a vascular replacement because the material is unable to withstand the pulsatile pressures involved, the same material certainly cannot perform as a heart valve prosthetic where the pulsatile pressures of the vascular system are even more severe.

Moreover, in order to anticipate Applicants' invention, a prior art document must contain all of the elements and limitations of the Applicants' rejected claim(s). There must be no difference between the claimed invention and the reference disclosure, as viewed by a person of ordinary skill in the field of the invention. *Scripps Clinic & Research Found. v. Genetech, Inc.*, 18 USPQ2d 1001, 1010 (Fed. Cir. 1991). Applicants respectfully traverse the anticipation rejection as to Dardik, as the cited reference fails to teach a material capable of providing, *inter alia*, the stable coaptation surface and resistance to vassicular pressures of Applicants' claimed invention. Accordingly, Applicants respectfully request the instant rejection be withdrawn.

As amended, independent claims 1 and 18 recite an implantable device for repairing a regurgitant cardiac valve comprising a structure configured for attachment to a prolapsing leaflet of the damaged valve at the prolapsing segment. Attaching Applicants' structure as claimed does not affect the effective valve area of the valve; i.e., the repaired valve has a valve area when opened that is

substantially the same as a healthy valve would be in the effected individual. The amended claims further define the physical characteristics providing a stable coaptation surface that reversibly coapts with an opposite leaflet during systolic contraction, and including a semi-rigid or rigid material sufficient to provide the stable coaptation surface and capable of withstanding pressures produced by movement of the valve leaflets and blood flow through the valve area.

Applicants respectfully submit that the Dardik material is incapable of providing the stable coaptation surface and of withstanding pressures produced by movement of the valve leaflets and blood flow through the valve area as required of the material recited in Applicants' amended claims because Dardik et al readily admit that the materials described in their patent cannot withstand the pulsatile pressures of a vascular system, as discussed in detail above. Therefore, Applicants respectfully submit that the instant rejection should be withdrawn.

REJECTIONS UNDER §102 – SAXON ET AL.

Claims 1, 5, 6-9, 12, 16-19 and 43-47 are rejected under 35 U.S.C. §102(b) as being anticipated by Saxon (U.S. Patent No. 5,725,577). With regard to Saxon, the Office Action states *in toto* that, "Saxon anticipates the claim language in that the device thereof would be inherently capable of functioning as the functional language implies; see Figure 6 and the abstract."

As a threshold issue, Applicants' respectfully direct the Office to *Ex parte Levy*, which reads in relevant part:

> "In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art."
>
> *Ex parte Levy*, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) (emphasis in original).

In the absence of a basis in fact and/or technical reasoning supporting the determination of inherency, the Office has failed to establish a *prima facie* case of anticipation/obviousness. The instant

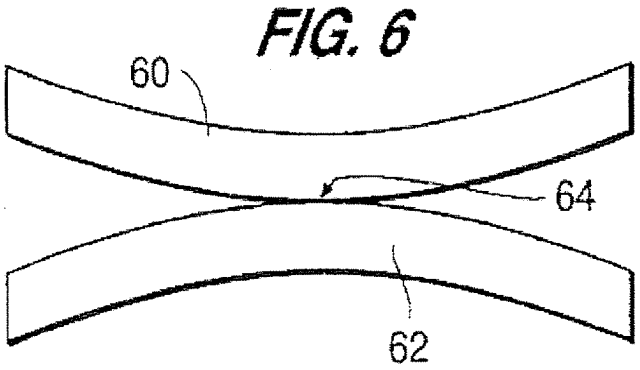
Office Action, and its predecessors, is void of any statement of fact or reasoning for the conclusion of anticipation based on inherency as to Saxon. Applicants therefore respectfully submit that the instant rejection is inappropriate as failing to present a *prima facie* case supporting the rejection and therefore the rejection as to Saxon should be withdrawn.

Notwithstanding, Applicants respectfully traverse the rejection as Saxon does not anticipate all elements of Applicants claims as amended. *Inter alia*, Saxon does not teach a device capable of providing the stable coaptation surface of Applicants' amended claims.

In an attempt to provide context to the instant rejection, Applicants provide Saxon figure 6 and abstract below. The Saxon abstract reads:

> "A prothesis for the repair of soft tissue defects is provided. The prosthesis is made of a first portion comprising a first material which substantially does not incorporate into the host tissue and a second portion comprised of a second material which substantially incorporates into the host tissue, or which increases the structural integrity of the prosthesis, or which does both. A process for repairing a soft tissue defect by surgically implanting the prosthesis is also provided."

Figure 6 is described beginning in Col. 7, line 66 as "...a view in cross-section of another embodiment of the present invention. The first portion 60 and the second portion 62 are joined partially along the interface 64 by any known method, as discussed above."



The first portion and second portion are described beginning at col. 4, line 48:

> "The prosthesis of the present invention comprises a first portion comprising a first material which substantially does not incorporate into the host tissue, and a second portion comprising a second material which substantially incorporates into the host tissue, or which increases the structural integrity of the prosthesis, or which does both."

Saxon clarifies the latter part of this description at col. 5, lines 42-50:

> "Alternatively, the second material can increase the structural integrity of the prosthesis by **reducing the effects of bulging, wrinkling and curling which may be associated with the first material.** Suitable second materials may both substantially incorporate into the host tissue and increase the structural integrity of the prosthesis. Examples of suitable second materials include polypropylene mesh, prolene mesh, or mersilene mesh." (emphasis added)

Saxon defines "substantially incorporate into the host tissue" beginning at Col.5, line 19 as:

> By "substantially incorporates into the host tissue," it is meant that, over time, the host tissue will grow substantially onto or substantially attach itself to the second material. Substantial incorporation is the type that is generally observed with repairs using polypropylene mesh. That is, with time the patient's fibrous and collagenous tissue substantially completely overgrow the mesh, growing through the openings therein and firmly affixing the mesh to the tissue. Eventually, it becomes difficult to recognize where the patient's tissue stops and the mesh begins.
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> Col 5, lines 19-29.

Thus as described by Saxon, the second portion of the device is embedded in the tissue of the patient, with the first portion partially joined to the second portion at an interface 64. Applicants respectfully submit that the grafts discussed in Saxon cannot provide the stable coaptation surface of Applicants' amended claims and therefore cannot anticipate Applicants' claimed invention. To illustrate, Applicants respectfully direct the Examiner to the construction of the Saxon graft. The portion of the Saxon device exposed when installed is the first portion, as the second portion is described as "substantially completely" imbedded into tissue. Therefore only the first portion could possibly interact with other structures and possess a stable coapting surface as presented in Applicants' claims. However, as noted above, Saxon's first portion is identified as only being partially joined to the second portion, and by inference to the underlying tissue, via an interface 64. The first portion is also identified as being

constructed from a material prone to bulging, wrinkling and curling. Applicants respectfully maintain that a material prone to bulging, wrinkling and curling and only partially attached to an underlying material that may reduce (but not eliminate) such effects is not a material capable of providing the stable coaptation surface of Applicants' amended claims.

Moreover, the Office has failed to identify how the Saxon graft is allegedly configured to be attached to a prolapsing segment in a manner that would repair the injured valve and prevent regurgitation, as recited in Applicants' claims. As previously noted, applying the Saxon graft according to Applicants' invention does not provide the necessary structural components of a prosthesis capable of preventing systolic regurgitation, as Saxon's second portion (a mesh) and first portion (PTFE) are only partially joined and therefore incapable of producing a competent valve.

Attaching the Saxon graft in the manner described by Saxon is equally futile as the Saxon graft would simply overlay existing tissue without addressing the prolapsed segment. (e.g., Compare Applicants disclosure, Figures 3-7 and Saxon figures 10-16). Accordingly, as Saxon fails to teach the stable coaptation surface and configuration for attachment of a device to a prolapsing valve leaflet in a manner producing a competent prosthetic, Saxon cannot anticipate Applicants' invention. Applicants therefore respectfully request the rejection as to Saxon be withdrawn.

REJECTIONS UNDER §103(A)

Claims 13 and 15 are rejected under 35 U.S.C. §103(a) as being unpatentable over Dardik *et al.* Applicants respectfully traverse and rebut the rejection.

Establishing a *prima facie* case for obviousness under §103 requires the Office to show, inter alia, that the references cited against Applicants teach or suggest all claim limitations of the rejected claim(s). *In re Royka*, 180 USPQ 580 (CCPA 1974); and MPEP §2143.03. As Applicants' previously noted in responding to the anticipation rejection as to Dardik, above, Dardik fails to teach all claim limitations of Applicants' amended claims. Applicants submit that comments as to relative dimensions are moot. Accordingly, Applicants traverse the rejection as to Dardik under §103 and respectfully request the rejection be withdrawn.

Moreover, Applicants respectfully note that Dardik teaches away from the proposed combination (see Dardik at Col. 5, lines 44-51, and explanations provided in response to the §102 rejection as to Dardik, above). Combination of a reference that teaches away is improper and fails to establish a prima facie case of obviousness. *In re Grasselli*, 713 F.2d 731, 743, 218 USPQ 769, 779 (Fed. Cir. 1983). Therefore, Applicant respectfully request the rejection as to Dardik under §103 be withdrawn.

CONCLUSION

Applicant submits that all of the claims are in condition for allowance, which action is requested. If the Examiner finds that a telephone conference would expedite the prosecution of this application, please telephone the undersigned at the number provided.

The Commissioner is hereby authorized to charge any underpayment of fees associated with this communication, including any necessary fees for extensions of time, or credit any overpayment to Deposit Account No. 50-0815, order number MSSM-001.

Respectfully submitted,
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Date: July 11, 2007

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